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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/722,574

11/28/2003

Allan Tanghoj

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EXAMINER

GILBERT, ANDREW M

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

04/15/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/722,574	<b>Applicant(s)</b> TANGHOJ ET AL.	
	<b>Examiner</b> ANDREW M. GILBERT	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-26 and 30-32 is/are rejected.
- 7) ☒ Claim(s) 27-29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/23/2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/6/09, 1/16/09</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS dated 11/12/2008</u> .             |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/27/2009 has been entered.

### ***Acknowledgements***

1. This office action is in response to the reply filed on 2/27/2009.
2. In the reply, the applicant cancelled all pending claims and filed new claims 21-32.
3. The applicant's arguments against the objection to the specification and 112 rejections of the claims are persuasive and the objection/rejections are hereby withdrawn.
4. The obvious double patenting rejection to US App. No. 10/537041 has been withdrawn because they case has gone abandoned.
5. Thus, claims 21-32 are pending for examination.

### ***Information Disclosure Statement***

6. The information disclosure statement (IDS) submitted on 11/12/2008, 1/16/2009, 2/6/2009 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 21-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Juster et al (3934721). Juster et al discloses a urinary catheter kit comprising: a distal catheter (35) section having an outlet at a distal end and a fastening mechanism (outward surface of beveled transition from 31 to 35) disposed proximate to a proximal end; a lubricated proximal catheter section (31) including an inlet (33c') proximate a proximal end and fixedly coupled with the distal catheter section (Fig 3-4) so that a distal end of the proximal catheter section is coupled with the proximal end of the distal catheter section; a conduit forming a fluid passageway from the inlet to the outlet; a tubular member (21) configured to enclose the lubricated proximal catheter section (Fig 3; col 2, lns 52-67) and including an attachment mechanism disposed at a distal end of the tubular member configured to releasably and sealingly engage the fastening mechanism to provide an enclosure around the lubricated proximal catheter section that is proximal to the fastening mechanism when the attachment mechanism is engaged with the fastening mechanism (The tubular member has an inner surface on its proximal end that contacts the gradually widening outer surface of the distal catheter. The inner surface and outer surfaces constitute the attachment and fastening mechanisms respectively. By frictional fit, they secure the tubular member and distal catheter. The

frictional fit is substantially a liquid tight seal (col 2, lns 52-67; wherein the interaction between the two prevents leakage of lubricant)); wherein the tubular member and the distal catheter section are positioned in an end to end relationship (Fig 3) with one another when the attachment mechanism is engaged with the fastening mechanism; wherein a proximal end of the tubular member is positioned adjacent to the proximal end of the lubricated proximal catheter section when the attachment mechanism is engaged with the fastening mechanism (Fig 3); wherein the engagement of the fastening mechanism with the attachment mechanism provides a fluid tight seal (col 2, lns 52-67; wherein the interaction between the two prevents leakage of lubricant); further comprising a liquid swelling medium disposed within the enclosure and the proximal catheter section includes a hydrophilic surface (col 2, lns 52-67); further comprising an outward flange disposed on the proximal end of the tubular member (27). Additionally, see response to arguments below.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Juster et al. Juster et al discloses the invention substantially as claimed except for expressly disclosing that the lubricant is water, saline, or a hydrogel. At the time the invention was made, it would have been an obvious matter of design choice to a person

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of ordinary skill in the art to have the lubricant be water, saline, or a hydrogel because the Applicant has not disclosed that having the lubricant be water, saline, or a hydrogel provides an advantage, is used for a particular purpose, or solves a stated problem.

Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with lubricant of Juster et al because it performs substantially the same function in substantially the same manner. Therefore, it would have been an obvious matter of design choice to modify Juster et al to obtain the invention as specified in claims 30-32.

### ***Double Patenting***

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 21-26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26, 54-65 of copending Application No. 10/184081. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the present application are merely broader than the copending parent case. Thus, the invention claimed in the current application is merely generic to the species claimed in the parent application and it has been held that the generic invention is anticipated by the species.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### ***Allowable Subject Matter***

4. Claim 27-29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Response to Arguments***

5. Applicant's arguments filed 2/27/2009 have been fully considered but they are not persuasive.

6. The applicant argues that Juster does not teach a tubular member having an attachment mechanism, a distal catheter having a fastening mechanism, nor a teaching of sealingly engaging one to the other.

7. The examiner respectfully disagrees. First, the applicant has recited no structure to either fastening mechanism or attachment mechanism. In their broadest reasonable interpretation, each mechanism simply needs to secure the tubular and distal catheter members. This is clearly met by Juster. The tubular member has an inner surface on its proximal end that contacts the gradually widening outer surface of the distal catheter. The inner surface and outer surfaces constitute the attachment and fastening mechanisms respectfully. By frictional fit, they secure the tubular member and distal catheter. The frictional fit is substantially a liquid tight seal (col 2, lns 52-67; wherein the interaction between the two prevents leakage of lubricant).

### ***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO 892 form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767